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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/736,051

12/13/2000

Hua Zhu Ke

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01/11/2005

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EXAMINER

LEARY, LOUISE N

ART UNIT

PAPER NUMBER

1654

DATE MAILED: 01/11/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/736,051	Applicant(s) KE ET AL.	
	Examiner Louise N. Leary	Art Unit 1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 9-24-2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) See Continuation Sheet is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1-4,6-14,16-30,33-42,45-50,52-55,57-62,65-69 and 72 is/are allowed.
- 6) ☒ Claim(s) 73-75,79,80,84-89 and 92-108 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Continuation of Disposition of Claims: Claims pending in the application are 1-4,6-14,16-30,33-42,45-50,52-55,57-62,65-69,72-75,79-80,84-89 and 92-108.

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1. Claims 1-4, 6-14, 16-30, 33-42, 45-50, 52-55, 57-62, 65-69, 72-75, 79-80, 84-89 and 92-108 are pending in this application.

Claims 5, 15, 31-32, 43-44, 51, 56, 63-64, 70-71, 76-78, 81-83 and 90-91 have been canceled per applicant's request.

2. The examiner acknowledges receipt of a courtesy copy of applicant's US Patent Application Serial No. 60/012,412, filed February 28, 1996, with the title "COMBINATION THERAPY FOR OSTEOPOROSIS".

3. The rejection of claims 73-75, 79-80, 84-89 and 92-108 under 35 U.S.C. 102(a) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Carpino et al (US 6,110,932 patented August 29, 2000 claiming priority to U. S. Provisional Application No. 60/009,469, filed Dec. 28, 1995) has been maintained for reasons of record.

4. Applicant's arguments filed September 24, 2004 have been fully considered but they are not persuasive.

Applicants have asserted "[The Patent Office applies Carpino et al. as prior art under 35 U.S.C. 102(a), citing the Carpino et al. issuance date of August 29, 2000 for its availability as prior art. Office Action, p.3.]" Albeit, the Carpino et al reference (U.S. Patent No. 6,110,932) was applied as prior art under 35 U.S.C. 102(a) and the publication August 29, 2000 date was included in the official office action, it is noted that

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the Carpino et al reference claims priority to U.S. Provisional application No.

60/009,469, filed Dec. 28, 1995. See the "Related U.S. Application Data" section on the Title page and column 1, lines 1-12 of the Carpino et al reference (U.S. Patent No. 6,110,932). It is noted that the U.S. Provisional application No. 60/009,469, filing date of Dec. 28, 1995 is earlier than applicant's February 28, 1996 priority date claimed in the instant application.

In addition, it is noted that the Carpino et al reference has been properly applied in the rejection of the claims under 35 U.S. C. 102(a) because the Carpino et al reference meets the statute requirements. Note the copy of the statute recited below.

"The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent."

Further, Carpino et al disclose or suggest the invention as claimed because Carpino et al disclose a pharmaceutical combination comprising a growth hormone secretagogue compound and estrogen agonist/antagonist. Specifically, Carpino et al disclose the growth secretagogue 2-amino-N-[2-(3a-(R)-benzyl-2-methyl-3-oxo-2,3,3a,4,6,7-hexahydro-pyrazolo-[4,3-c]pyrindin-5-yl)-1-(R)-benzyloxymethyl-2-oxo-ethyl]-isobutyramide and the L-tartaric salt in combination with an estrogen agonist/antagonist to treat osteoporosis. Again, note the abstract; column 20, lines 46-59 and column 30, lines 58-64.

Therefore, Carpino et al disclose or suggest that the subject matter regarded as the invention was known or used by others in this country before the instant invention was made by applicants.

For the reasons given above the rejection of the claims has been maintained.

5. Claims 1-4, 6-14, 16-30, 33-42, 45-50, 52-55, 57-62, 65-69 and 72 are allowable over the prior art of record.

6. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

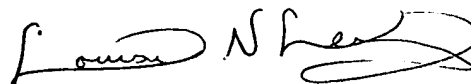
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Louise N. Leary whose telephone number is (571) 272-0966. The examiner can normally be reached on Monday to Friday from 10 to 6:30.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campbell, can be reached on (571) 272-0974. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A handwritten signature in black ink, appearing to read "Louise N. Leary", with a stylized flourish at the end.

Louise N. Leary
Primary Examiner
Art Unit 1654
January 8, 2005